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PATENT

Attorney Reference Number 6235-59221
Application Number 09/869,475

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: Morishita

Art Unit: 1635

Application No. 09/869,475

Confirmation No.: 4309

Filed: June 28, 2001

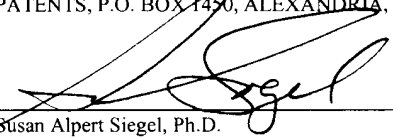
CERTIFICATE OF MAILING

For: GENE THERAPY FOR DIABETIC
ISCHEMIC DISEASE

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on August 13, 2003 as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Examiner: Brian A. Whiteman

Date: August 13, 2003



Susan Alpert Siegel, Ph.D.
Agent for Applicant

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DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Ryuichi Morishita, am a co-inventor named in the above-referenced patent application.

2. I have read and understand the above-referenced patent application, including the pending claims, and the Office action dated May 13, 2003. Claims 1-12 and 15-20 are rejected as being obvious over Gene Therapy of Osaka University, English translation from the Japan Financial Newspaper, Local News Section (December 14, 1998). This article was published less than one year before the priority application, Japanese Patent Application No. 11/309984, was filed.

3. The article published in the Japan Financial Newspaper is a report of my own work. I worked as an Assistant Professor in the Division of Gene Therapy Science at Osaka University Medical School at the time the article was written, and at the time the invention disclosed in the above-referenced application was made.

4. As described in the article, arteriosclerosis obliterans caused by diabetes mellitus is a very serious disease. In the worst case, patients must undergo drastic therapies such as limb amputation. I and my co-inventor, Toshio Ogihara, established a method of treatment of this disease that does not require that a limb be amputated. This work was performed in the Division of Gene Therapy Science at Osaka University. Due to the important clinical implications of this work, we decided to proceed with a clinical trial so that patients could immediately receive the benefit of this important therapy. To initiate a clinical trial in Japan it is required to obtain approval from the Institutional Review Board (IRB) at Osaka University, and then to obtain approval from the Japanese Health Authority. The article in the Japan Financial News reports that our request for approval from the Institutional Review Board (IRB) at Osaka University was filed. Clearly, as this is a report of my own work, my invention was conceived prior to the publication of the article in the Japan Financial Newspaper.

5. I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Ryuichi Morishita, M.D., Ph.D.

Date